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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,108	10/16/2003	Ryan A. Kaiser	5490-000345	7219
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HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER HUANG, LIAN	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 03/18/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,108

Applicant(s)

KAISER ET AL.

Examiner

LIAN HUANG

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10-21,24-28,30-41 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-21,24-28,30-41 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 4 August 2008. Claims 2, 7, 9, 22, 23, 29, and 42 have been canceled without prejudice. Claims 1-6, 8, 10-21, 24-28, 30-41, and 43-47 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-6, 8, 10, 12-21, 24-27, and 30-41, 43-47 are rejected under 35 U.S.C. 102(b) as being disclosed by **Scarborough et al. (US 5,632,747)**.

Regarding claim 1, Scarborough et al. disclose (Figs. 19-23) an apparatus for harvesting a bone core, comprising:

a collet assembly (300);

a sleeve (310) defining an internal bore (312);

a collar (332) disposed within said internal bore; and

a biasing member (330) within said sleeve providing a biasing force on said collar (figure 22);

a chuck engageable member (28) extending from said collet assembly operable to interconnect a selected chuck with said collet assembly; and

a harvesting member (40) selectively engageable with said collet assembly;

wherein said collar is moveable, within said sleeve, between an engaged position and a non-engaged position (column 7, lines 13-41, where the collar is engaged when it is secured with part 340 (130), and non-engaged when it is not).

wherein said harvesting member further contacts said collar and is able to move said collar between said engaged position and said non-engaged position (where "engaged" is when the parts are assembled, and "non-engaged" refers to when the parts are disassembled);

wherein said harvesting member is able to move said collar generally with a manual force (column 7, lines 14-41, where manual force is implicit).

Regarding claim 3, Scarborough et al. disclose the apparatus as stated above wherein when said harvesting member has moved said collar to said engaged position said harvesting member is selectively held within a portion of said internal bore (figure 22, where harvesting member 40 is held within portion 316 of bore 312).

Regarding claim 4, Scarborough et al. disclose the apparatus as stated above wherein said collar (332) is operable with said sleeve (310) to define a substantially quick connect interaction (where all the parts being threadably received defines a substantially quick connect interaction) wherein said harvesting members are able to quick connect with said collet assembly to provide a selected interconnection (column 5, lines 55-64) between said harvesting member and said collet assembly.

Regarding claim 5, Scarborough et al. disclose the apparatus as stated above further comprising:

a graspable member (20) including a chuck (28) extending from said graspable member to engage said chuck engageable member (314); wherein said chuck engages said chuck engageable member during the harvesting of the bone core (column 6, lines 45-46).

Regarding claim 6, Scarborough et al. disclose the apparatus as stated above wherein said graspable member includes a drill motor (20) able to rotate said collet after said chuck (28) engages said chuck engageable member (314).

Regarding claim 8, Scarborough et al. disclose the apparatus as stated above wherein said graspable member includes a manually operable handle (20) and a chuck (28) extending from said manually operable handle (figure 19);

wherein said chuck (28) is able to engage said chuck engageable member (314) to operably interconnect said collet with said manually operable handle to allow for harvesting of the bone core (column 6, lines 45-46).

Regarding claim 10, Scarborough et al. disclose the apparatus as stated above wherein said harvesting member (40) is substantially cylindrical in shape and defines an internal bore; wherein said sharpened end includes a sharpened edge defined by an edge of said cylinder; wherein the cutting end is able to cut the bone core and collect it within said internal bore (figure 22);

wherein a passage bore is defined by said collet assembly and said chuck engageable member (314) is substantially coaxial with said internal bore (figure 19).

Regarding claim 12, Scarborough et al. disclose the apparatus as stated above further comprising:

a plunger (320) to assist in removing the bone core from said harvesting member;

wherein said harvesting member (40) defines an internal bore in which said plunger is disposable;

wherein the bone core is collected within said harvesting bore and said plunger is operable to extract the bone core from said harvesting member (please compare figures 21 and 22).

Regarding claim 13, Scarborough et al. disclose the apparatus as stated above wherein said harvesting member (40) defines a cannula and substantially equal in a dimension throughout said harvesting member.

Regarding claim 14, Scarborough et al. disclose the apparatus as stated above wherein said harvesting member includes a first and a second end;

wherein the bone core may be removed from either of said first end or second end (column 7, lines 25-32; please compare figures 22 and 23).

Regarding claim 15, Scarborough et al. disclose an apparatus for harvesting and implanting a bone core, comprising:

a collet assembly (310) including a selectively engageable mechanism and defining an internal bore;

a harvester (40) to selectively engage said selectively engageable mechanism and to be disposed within said internal bore, said harvester defining a harvester bore (figure 20);

a graspable assembly (20) to selectively engage said collet and defining a graspable assembly bore (28) that is generally aligned with said harvester bore when said graspable assembly selectively engages said collet assembly;

wherein said graspable assembly includes both a drill motor (20) and a handle (figure 19) wherein said drill motor individually selectively engages said collet assembly (column 4, lines 10-14, wherein said selectively engageable mechanism includes a generally quick-release mechanism (where the components are all threadably received, thus comprising a generally-quick-release mechanism) wherein said harvester is engageable and disengageable from said selectively engageable mechanism with pressure from the user (column 7, lines 34-40).

Regarding claim 16, Scarborough et al. disclose the apparatus as stated above further comprising:

a plunger (324) moveable within said graspable assembly bore and said harvester bore;

wherein said plunger is operable with said harvester bore during a harvesting of the bone core;

wherein said collet is disengageable from said graspable assembly and said plunger is operable to remove the bone core from said harvester (figures 22 and 23).

Regarding claim 17, Scarborough et al. disclose the apparatus as stated above wherein said collet assembly includes:

- a sleeve (310) defining an internal bore (312),
- a collar (332), disposed within said internal bore; and
- a biasing member (330) within said sleeve providing a biasing force on said collar.

Regarding claim 18, Scarborough et al. disclose the apparatus as stated above further including:

- a pin (340) extending from said collar (332, where "extending from" is taken to mean "extending away") to engage said harvester such that a torque applied to said collet is transferred to said harvester (column 6, lines 45-47, where one end of the collar engages the drill, and the other end connects with the harvester, so torque applied to the collet must be transferred to the harvester);

- wherein said collar (332) is slideable within a bore defined by said sleeve when acted upon by said harvester (please compare figures 21-23);

- wherein said collar is biased in a first position by a compression spring (330) disposed between said collar and said sleeve.

Regarding claim 19, Scarborough et al. disclose the apparatus as stated above wherein said harvester includes a collet engaging end and a harvesting end (figure 19);

- wherein said harvesting end includes a sharpened portion to cut a selected portion of a bone to harvest the bone core;

wherein said harvester is operable to collect the bone core within said harvester bore (column 7, lines 19-21; figure 22).

Regarding claim 20, Scarborough et al. disclose the apparatus as stated above wherein said sharpened end includes at least one of a sawtooth and a generally planar edge (part 40, figures 20-22).

Regarding claim 21, Scarborough et al. disclose the apparatus as stated above wherein the bone core may be removed from either of said collet engaging end and said harvesting end (figures 22 and 23; column 7, lines 26-33).

Regarding claim 24, Scarborough et al. disclose the apparatus as stated above wherein the bone core is collectible within said harvester bore and said plunger (324) is operable to remove the bone core from said harvester bore (figure 23).

Regarding claim 25, Scarborough et al. disclose the apparatus as stated above wherein said plunger (324) is able to push the selected bone portion into a selected position from the harvester substantially directly from the harvester (figure 23).

Regarding claim 26, Scarborough et al. disclose the apparatus as stated above wherein said harvester bore (40) is substantially equal in at least one dimension throughout (figures 19-22).

Regarding claim 27, Scarborough et al. disclose a method of harvesting and implanting a bone core, comprising:

interconnecting a harvesting member (40) with a collet member in a quick-release manner, including operably contacting said harvesting member (40) with a

biasing member (330) and providing a biasing force on said harvesting member (column 7, lines 14-24);

interconnecting said collet (310) and a graspable member (20);

driving said harvesting member into a selected bone portion; trapping a selected length of bone within said harvesting member (figure 20); and

removing said selected length of bone from said harvesting member into a selected location (figure 22).

Regarding claim 30, Scarborough et al. disclose the method as stated above wherein interconnecting said collet (310) with a graspable member (20) includes selectively connecting said collet to a drill motor such that said drill motor is able to rotate said collet (column 4, lines 10-14 and column 7, lines 34-40, where selective locking is shown by the selectively coupled members).

Regarding claim 31, Scarborough et al. disclose the method as stated above wherein driving said harvesting member includes:

rotating said harvesting member with said drill motor (column 2, lines 1-11); and
pressing said harvesting member into the selected bone portion to remove the selected length of bone into said harvesting member (column 1, lines 49-64) .

Regarding claim 32, Scarborough et al. disclose the method as stated above further comprising:

disposing said harvesting member with said trapped selected length of bone relative to an implant site; and

wherein removing said selected length of bone includes pushing said selected length of bone into the implant site (figure 22; column 7, lines 25-33, where "into" is taken to mean "in the direction of").

Regarding claim 33, Scarborough et al. disclose the method as stated above further comprising:

disposing a plunger (324) through at least a portion of said harvesting member (40); wherein removing said selected length of bone includes pushing said selective length of bone from said harvester into the implant site with the plunger (figure 22; column 7, lines 25-33, where "into" is taken to mean "in the direction of").

Regarding claim 34, Scarborough et al. disclose the method as stated above wherein the harvesting member (40) includes a first end and a second end, wherein removing said selective length of bone includes removing the selected length of bone from at least one of the first end and the second end (figure 23).

Regarding claim 35, Scarborough et al. disclose an instrument for harvesting a selected bone core, comprising:

a graspable member (20) operable to be grasped by a user;

a harvest member (40) operable with said graspable member to harvest the selected bone core;

a connecting member (310) operable to selectively interconnect said graspable member and said harvest member;

wherein said connecting member includes a spring biasing member (330) providing a biasing force on said harvest member, said connecting member and a

bearing member (316) to interconnect in a substantially quick-release manner at least one of said graspable member and said harvest member.

Regarding claim 36, Scarborough et al. disclose an instrument as stated above wherein said graspable member (20) includes at least one of an impact handle and a drill motor.

Regarding claim 37, Scarborough et al. disclose an instrument wherein said harvest member (40) includes a cannula including a cutting end including at least one of a sharpened edge and a saw tooth.

Regarding claim 38, Scarborough et al. disclose an instrument wherein said connecting member (316 part of 310) connects with said harvest member; wherein said harvest member can be engaged and disengaged from said connecting member with a substantially axial motion alone.

Regarding claim 39, Scarborough et al. disclose an instrument wherein said harvest member is removably coupled to said a connecting member (column 6, lines 46-47 and column 7, lines 34-40).

Regarding claim 40, Scarborough et al. disclose an instrument wherein said graspable member is removably coupled to said a connecting member (part 314 of 310; column 6, lines 45-46).

Regarding claim 41, Scarborough et al. disclose an instrument forming a selected core of a bone, comprising:

a harvesting member (40) operable to be driven into a selected portion of bone; said harvesting member defining a cannula including a dimension substantially equal throughout a length of said harvesting member; and

a graspable portion (20) extending from said harvesting member such that said harvesting member can be positioned relative to a selected portion of bone for forming the bone core; and

a collet portion (310) including a biasing member (330), a collar (332), and a bearing member (316);

wherein the biasing member (330) provides a biasing force on said harvesting member and said collar to operably interconnect said harvesting member and said graspable portion (please compare figures 20-23);

wherein said bearing member (316) contacts the collar (332) to hold the collar in a selected position and hold the harvesting member relative to the graspable portion.

Regarding claim 43, Scarborough et al. disclose an instrument further comprising: a plunger member (324); wherein said plunger member is operable to be moved through said internal cannula to remove the selected bone core from the cannula (column 7, lines 35-39).

Regarding claims 44 and 45, Scarborough et al. disclose the apparatus as stated above wherein the collet assembly further includes a bearing (316) to engage an aperture formed in said harvesting member in said engaged position (figure 19),

wherein said harvesting member (40) includes:

a first harvesting member having distal teeth (figure 19); and

a second harvesting member having a smooth driveable end (312).

Regarding claim 46, Scarborough et al. disclose the apparatus as stated above wherein the graspable assembly (20) includes a driveable handle and a drill motor;

Wherein said driveable handle is operable to be struck to drive said harvester with a planar edge substantially axially into a surface and maintain a core of a material within the harvester (figure 22);

wherein the drill motor is operable to rotate said harvester with said saw tooth edge into a surface and maintain a core of material within the harvester (column 4, lines 10-15; column 5, lines 13-24).

Regarding claim 47, please refer to claim rejection 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scarborough et al. (US 5,632,747)** in view of **"Autogenous Bone Coring: a Scientific Approach"** by Arthrotek, Inc. and Schmidt, 2004.

Regarding claim 11, Scarborough et al. disclose the apparatus as stated above, but fail to teach it further comprising a mallet to strike said manually operable handle

(20) to drive a selected end of said harvesting member (40) into a bone to harvest the bone core.

However, Schmidt teaches striking a handle with a mallet to position an instrument (figure 14).

It would be obvious to one of ordinary skill in the art at the time of the invention to use a mallet to drive the harvesting member into a bone as taught by Schmidt in order to provide the force necessary to position and anchoring the instrument relative to the desired location on the bone before the cutter being operated.

Regarding claim 28, Scarborough et al. disclose the method as stated above wherein interconnecting said collet (310) with a graspable member (20) includes selectively locking (column 6, lines 40-47 and column 7, lines 34-40, where selective locking is shown by the selectively coupled members) said collet member (310) to a graspable handle (20) that is strikeable with a mallet, but

fails to teach it wherein driving said harvesting member includes striking said graspable member (20) with a mallet to drive said harvesting member (40) into the selected bone portion.

However, Schmidt teaches striking a handle with a mallet to position an instrument (figure 14).

It would be obvious to one of ordinary skill in the art at the time of the invention to use a mallet to drive the harvesting member into a bone as taught by Schmidt in order to provide the force necessary to position and anchoring the instrument relative to the desired location on the bone before the cutter being operated.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8, 10-21, 24-28, 30-41, and 43-47 have been considered, however, upon further consideration of **Scarborough et al.** reference, the claims stand rejected by the embodiment shown in Figs. 19-22 of Scarborough's drawings.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIAN HUANG whose telephone number is (571)270-3987. The examiner can normally be reached on 7:30 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/14/09